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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,582

02/17/2004

Jane P. Bearinger

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2811

24981

7590

03/09/2009

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EXAMINER

ANDERSON, GREGORY A

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

03/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,582	<b>Applicant(s)</b> BEARINGER ET AL.	
	<b>Examiner</b> GREGORY A. ANDERSON	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6,11-17,19-21,25,31,32,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,11-17,19-21,25,31,32,34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. In view of the appeal brief filed on 17 November 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/s/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 1, 4, 5, 11, 12, 14, 16, 17, 19-21, 25, 31, 32, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. 5,549,633 in view of Bleys et al. 6,034,149.

Evans et al. discloses an apparatus for closure of an arterial puncture comprising: a closure body 22, the closure body being made of foam formed into a primary shape and compressed into a reduced secondary stable shape and then controllably actuated to that it recovers its primary shape (Figs. 10-12), a delivery catheter 20 adapted to receive the closure body and adapted to deploy the closure body into the physical anomaly, wherein the foam of the closure body in the secondary shape is configured for positioning the closure body within the anomaly (Fig. 10), and wherein the foam is controllably actuated so that it recovers its primary shape with the primary shape being configured to close the anomaly (Fig. 12). Evans et al. further discloses a plunger 28 for controllably actuating the foam and a tube 26. The foam of Evans et al. takes the form of the container it is in, i.e. a tubular shape when it is within the deployment device and a shape conforming to the tissue surrounding the closure body when deployed, and thus has similar shape to that which a flowing fluid would have in the same scenarios. Further, the foam of Evans et al. has a volume larger than the gap in the vascular wall (Fig. 12) when deployed and smaller than the gap (Fig. 9) when being delivered.

However, Evans et al. does not disclose the foam of the closure body being formed from a shape memory polymer having at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above the glass

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transition temperature and the soft segment is formed at a temperature below the glass transition temperature. Evans et al. further does not disclose transitioning the closure body to its primary shape by changing the temperature above the glass transition temperature in order to close the anomaly.

Bleys et al. discloses shape memory foam comprising polycaprolactone, polyesters, and biodegradable linkages comprising ester (Col. 5 ll. 19-47, Col. 1 ll. 12-15). Bleys et al. further discloses hard and soft segments (Col. 1 ll. 12-31), the hard segments being formed at temperatures above the glass transition temperature, the soft segments being formed at temperatures below the glass transition temperatures. Further Bleys et al. discloses cooling the foam to a temperature below the glass transition temperature while in the smaller volume condition (Col. 1 ll. 32-37). Further Bleys et al. discloses heating the foam to above its glass transition temperature to transition the foam into its primary shape (Col. 1 ll. 32-37). Further, Bleys et al. discloses using shape memory foams in medical applications (Col. 6 ll. 46-56).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. by using the shape memory foam of Bleys et al. in order to provide a foam that exhibits good absorption and retention characteristics, good wicking properties, stability, and simplicity of chemicals to ensure a minimum of leachable substances in contact with the human body as taught by Bleys et al. (Col. 6 ll. 40-51).

4. Claims 6, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. in view of Bleys et al. and further in view of Duane et al. 5,836,306.

Evans et al. in view of Bleys et al. discloses the invention essentially as claimed as discussed above.

However, Evans et al. in view of Bleys et al. does not disclose a restraint tube for backbleed measurement.

Duane et al. discloses a restraint tube 14 for the measurement and control of backbleed.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Evans et al. in view of Bleys et al. with the restraint tube of Duane et al. in order to provide backbleed control during and after placement of a catheter within a patient's vascular system as taught by Duane et al. (Col. 2 ll. 44-49).

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 have been considered but are moot in view of the new ground(s) of rejection. In an effort to expedite prosecution, the Examiner will herein try to clarify some of the applicants arguments submitted during appeal: Applicant has argued that the device of Evans et al. is not intended to close a physical anomaly in a vascular wall. Examiner disagrees. While the foam of Evans et al. does not close the gap in the vessel, the Evans device clearly does. The suturing aspect of the Evans et al. device pulls the vessel walls together and is subsequently sealed by the insertion of the foam member. Further, the device of Evans et al. is capable of being inserted within the vessel and if so placed would perform in the same manner as if it is placed slightly above the vessel in the overlying tissue as disclosed by Evans et al. Applicant further argues that the

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Evans et al. and Bleys et al. references do not disclose all of the limitations of the claims. All of the limitations of the claims have been addressed as indicated in the above office action. Further, since the Bleys et al. reference clearly discloses its intended use in medical applications (Col. 6 ll. 46-56) there would be reasonable expectation of success in substituting the non memory foam of Evans et al. with the shape memory foam of Bleys et al..

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773